

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No.: 13/082-1-D1

Application of: Thibeault, D. et al

) Art Unit: 1648

Serial No. : To be assigned

) Examiner: To be assigned

Filed : August 28, 2003

) Conf. No.: To be assigned

For : Purified Active HCV NS2/3 Protease

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

August 28, 2003

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement under 37 C.F.R. §§1.56 and 1.97. The cited references and a copy of the International Search Report for the foreign counterpart of the parent application can be found in the file of the parent application, U.S. Serial No. 10/017,736, filed December 14, 2001.

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

- A statement as specified in 37 C.F.R. §1.97(e) [see below]; or
- The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

1.97(e).

Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

The fee set forth in 37 C.F.R. §1.17(p).

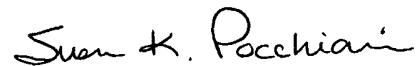
The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



Susan K. Pocchiari
Attorney for Applicant(s)
Reg. No. 45,016

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 798-4868

<p>Substitute for form 1449A/PTO</p> <p>PATENT DOCUMENTS SUBMITTED BY APPLICANT</p>				Complete If Known	
				Application Number	To be assigned
				Filing Date	August 28, 2003
				First Named Inventor	Thibeault, Diane
				Group Art Unit	1648
				Examiner Name	To be assigned
Sheet	1	of	4	Attorney Docket Number	13/082-1-D1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
AUS1		5,714,371		Ramanathan	02-03-1998	
AUS2						
AUS3						
AUS4						
AUS5						
AUS6						
AUS7						
AUS8						
AUS9						
AUS10						
AUS11						
AUS12						
AUS13						
AUS14						
AUS15						
AUS16						
AUS17						
AUS18						
AUS19						
AUS20						

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (if known)				
AF1		WO 01/16379		Merck & Co., Inc.	03-08-2001		<input type="checkbox"/>	
AF2		WO 01/68818		ISTI-TUTO Di Ricerche Di Biologia Molecolare P. Angeletti	09-20-2001		<input type="checkbox"/>	
AF3		WO 99/07733		Boehringer Ingelheim Canada Ltd.	02-18-1999		<input type="checkbox"/>	
AF4		WO 97/08304		Istituto Di Ricerche Di Biologia Molecolar S.P.A.	03-06-1997		<input type="checkbox"/>	
AF5							<input type="checkbox"/>	
AF6							<input type="checkbox"/>	
AF7							<input type="checkbox"/>	
AF8							<input type="checkbox"/>	
AF9							<input type="checkbox"/>	
AF10							<input type="checkbox"/>	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449B/PTO				Complete If Known	
NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT				Application Number	To be assigned
				Filing Date	August 28, 2003
				First Named Inventor	Thibeault, Diane
				Group Art Unit	1648
				Examiner Name	To be assigned
Sheet	2	of	4	Attorney Docket Number	13/082-1-D1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
---	--	--	--	--	--

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published				T
	AO1	CHIRGWIN, PRZYBYLA et al.; Isolation of Biologically Active Ribonucleic Acid from Sources Enriched in Ribonuclease; Biochemistry; 1979, v. 18; 5294-5299				<input type="checkbox"/>
	AO2	DARKE, JACOBS et al.; Inhibition of Hepatitis C Virus NS2/3 Processing by NS4A Peptides; J. Biol. Chem.; 1999, V. 274, No. 49; 34511-34514				<input type="checkbox"/>
	AO3	GRAKOU, MCCOURT et al.; A second hepatitis C virus-encoded proteinase; Proc. Natl. Acad. Sci. USA; 1993, V. 90; 10583-10587				<input type="checkbox"/>
	AO4	KOLYKHALVO, MIHALIK et al.; Hepatitis C Virus-Encoded Enzymatic Activities and Conserved RNA Elements in the 3' Nontranslated Region are Essential for Virus Replication In Vivo; 2000, V. 74, No. 4; 2046-2051				<input type="checkbox"/>
	AO5	LIN, TIMASHEFF; On the role of surface tension in the stabilization of globular proteins; Protein Sci.; 1996, V. 5; 372-381				<input type="checkbox"/>
	AO6	LIU, BHAT et al.; The Hepatitis C Virus NS2 Protein Generated by NS2-3 Autocleavage is Required for NS5A Phosphorylation; Biochem. Biophys. Res. Commun.; 1999, V. 254; 572-577				<input type="checkbox"/>
	AO7	NEDDERMANN, CLEMENTI et al.; Hyperphosphorylation of the Hepatitis C Virus NS5A Protein Requires an Active NS3 Protease, NS4A, NS4B, and NS5A Encoded on the Same Polyprotein; J. Virol.; 1999, V. 73, No. 12; 9984-9991				<input type="checkbox"/>
	AO8	PALLAORO, LAHM et al.; Characterization of the Hepatitis C Virus NS2/3 Processing Reaction by Using a Purified Precursor Protein; J. Virol.; 2001, V. 75, No. 20; 9939-9946				<input type="checkbox"/>
	AO9	PIERONI, SANTOLINI et al.; In Vitro Study of the NS2-3 Protease of Hepatitis C Virus; J. Virol.; 1997, V. 71, No. 9; 6373-6380				<input type="checkbox"/>
	AO10	REED, GRAKOU et al.; Hepatitis C Virus-Encoded NS2-3 Protease: Cleavage-Site Mutagenesis and Requirements for Bimolecular Cleavage; J. Virol.; 1995, V. 69, No. 7; 4127-4136				<input type="checkbox"/>
	AO11	SANTOLINI, PACINI et al.; The NS2 Protein of Hepatitis C Virus is a Transmembrane Polypeptide; J. Virol.; 1995, V. 69, No. 12; 7461-7471				<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449B/PTO				Complete If Known	
NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT				Application Number	To be assigned
				Filing Date	August 28, 2003
				First Named Inventor	Thibeault, Diane
				Group Art Unit	1648
				Examiner Name	To be assigned
Sheet	3	of	4	Attorney Docket Number	13/082-1-D1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	AO1	THIBEAULT, MAURICE et al.; In Vitro Characterization of a Purified NS2/3 Protease Variant of Hepatitis C Virus; J. Biol. Chem.; 2001, V. 276, No. 49; 46678-46684	<input type="checkbox"/>
	AO2	WALKER, M.A.; Hepatitis C virus: an overview of current approaches and progress; Drug Discovery Today; 1999; V. 4, No. 11; 518-529	<input type="checkbox"/>
	AO3	DYMOCK, JONES et al.; Novel approaches to the treatment of hepatitis C virus infection; Antiviral Chemistry & Chemotherapy; 2000; V. 11(2); 79-96	<input type="checkbox"/>
	AO4	GORBALENYA, SNIJDER; Viral cysteine proteinases; Perspect. Drug Discovery Design; 1996; V. 6; 64-86	<input type="checkbox"/>
	AO5	HIJIKATA, MIZUSHIMA et al.; Two Distinct Proteinase Activities Required for the Processing of a Putative Nonstructural Precursor Protein of Hepatitis C Virus; J. Virol; 1993; V. 67, No. 8; 4665-4675	<input type="checkbox"/>
	AO6	HIROWATARI, HIJIKATA et al.; Two proteinase activities in HCV polypeptide expressed in insect cells using baculovirus vector; Arch. Virol.; 1993; V. 133; 349-356	<input type="checkbox"/>
	AO7	KOMODA, HIJIKATA et al.; Processing of hepatitis C viral polyprotein in Escherichia coli; Gene; 1994; V. 145; 221-226	<input type="checkbox"/>
	AO8	WADA, WADA et al.; Codon usage tabulated from the GenBank genetic sequence data; Nuc. Acids Research; 1992; V. 20; 2111-2118	<input type="checkbox"/>
	AO9	WONG, ALBRIGHT, et al.; Immobilized Metal Ion Affinity Chromatography (IMAC) - Chemistry and Bioseparation Applications; Separation and Purification Methods; 1991; V. 20(1); 49-106	<input type="checkbox"/>
	AO10	AUSUBEL, BRENT et al.; Current Protocols in Molecular Biology; 1994; Vol. 1, 2, 3 and 4; Wiley, New York	<input type="checkbox"/>
	AO11	SAMBROOK, FRITSCH et al.; Molecular Cloning - A Laboratory Manual, Second Edition; 1989; Cold Spring Harbor Laboratory Press	<input type="checkbox"/>

Examiner Signature		Date Considered
--------------------	--	-----------------

Substitute for form 1449B/PTO NON-PATENT DOCUMENTS SUBMITTED BY APPLICANT				Complete If Known		
Sheet		4	of	4	Application Number	To be assigned
					Filing Date	August 28, 2003
					First Named Inventor	Thibeault, Diane
					Group Art Unit	1648
					Examiner Name	To be assigned
					Attorney Docket Number	13/082-1-D1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
--	--	--	--	--	--	--

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	AO1	CHEMELLO, CAVALLETTO et al.; The effect of interferon alfa and ribavirin combination therapy in naïve patients with chronic hepatitis C; J. Hepatology; 1995; V. 23. Suppl. 2; 8-12	<input type="checkbox"/>
	AO2	WENZEL, TROXELL et al.; Establishment of a Cell-Based Assay for Evaluation of Compounds against HCV NS2-3 Protease Activity; Prog. & Abstr. Interscience Conf. Antimicrobial Agents & Chemo.; 199; V. 39; 409	<input type="checkbox"/>
	AO3	PCT International Search Report of rPCT/CA 01/01796 International Filing Date Dec. 13, 2001	<input type="checkbox"/>
	AO4		<input type="checkbox"/>
	AO5		<input type="checkbox"/>
	AO6		<input type="checkbox"/>
	AO7		<input type="checkbox"/>
	AO8		<input type="checkbox"/>
	AO9		<input type="checkbox"/>
	AO10		<input type="checkbox"/>
	AO11		<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--